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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,995	09/22/2003	Douglas M. Coldwell	2024728-7032762001 (03-15)	1753
7590	09/30/2005		EXAMINER PEFFLEY, MICHAEL F	
Bingham McCuthen, LLP Suite 1800 Three Embarcadero San Francisco, CA 94111-4067			ART UNIT 3739	PAPER NUMBER

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/668,995	<b>Applicant(s)</b> COLDWELL ET AL.	
	<b>Examiner</b> Michael Peffley	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/22/03; 1/31/05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Tu et al (6,231,570).

Tu et al disclose a device and method for treating tissue. In use, a plurality of electrodes (13) are advanced from the distal end of a cannula (1) such that the electrodes lie within the same plane (see Figure 1). The electrodes are placed in contact with tissue and RF energy is delivered from the electrodes to treat tissue (see Abstract).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al (6,231,570) in view of the teaching of LeVeen et al (6,575,967).

Tu et al disclose a device that comprises a catheter (1) having a plurality of electrodes disposed within the lumen of the catheter and deployable from the distal end substantially perpendicular to the longitudinal axis of the catheter (see Figure 4). The

electrodes, when deployed, form a flat plane and also include a curved section (i.e. where they are deployed from the catheter). The tips of the electrode are blunt, and the device is provided to tissue and the electrodes are deployed to contact tissue on a flat plane. The only feature not expressly taught by Tu et al is the use of a substantially rigid cannula from which the electrodes are deployed. Rather, the Tu et al catheter is flexible.

LeVeen et al disclose a substantially analogous device including a flexible catheter having a plurality of electrodes deployable therefrom (Figure 1). In particular, LeVeen et al teach that it is advantageous to provide a rigid cannula for providing the device to tissue (Figures 10-15). The rigid cannula has a blunt distal tip (Figures), but may include a sharpened distal tip if desired (col. 10, lines 24-26).

To have provided the Tu et al device with a rigid cannula for providing the device to a desired tissue site would have been an obvious consideration for one of ordinary skill in the art, particularly since LeVeen et al teach that it is known to rigid trocars for providing deployable electrode devices to a treatment site.

Claims 9-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al ('570) and LeVeen et al ('967) as applied to claims 1-8 above, and further in view of the teaching of Balbierz et al (6,770,070).

The combination of the Tu et al and LeVeen et al references has been previously addressed. In short, LeVeen et al teach that it is known to use a rigid cannula to provide a flexible, deployable electrode assembly to tissue. However, neither Tu et al

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nor LeVeen et al specifically disclose treating tumor tissue in a pleura. It is noted that the LeVeen et al device, which is structurally very similar to the Tu et al device, is used for the treatment of tumors, albeit not specifically in lung tissue.

The examiner maintains that the use of a device such as taught by Tu et al and/or LeVeen et al to treat any type of tumorous tissue would be an obvious consideration for one of ordinary skill in the art. In support of this assertion, attention is directed to the Balbierz et al system. Balbierz et al also disclose an electrosurgical device that includes a plurality of electrodes deployable from an elongate member for the treatment of tumors. The Balbierz et al deployable electrode device is substantially analogous to both the LeVeen et al and the Tu et al devices. In particular, Balbierz et al teach that the device may be used to treat tumors in any lung tissue (col. 8, lines 5-15). The Balbierz et al device includes a plurality of electrodes deployable from a rigid cannula (Figures 12 and 14-18) and is structurally very similar to both the Tu et al and LeVeen et al devices.

In conclusion, to have used the Tu et al device, as modified by the teaching of LeVeen et al, to treat tissue in the lung would have been an obvious consideration for one of ordinary skill in the art, particularly since Balbierz et al teach that it is known to use a structurally analogous device for the treatment of lung tumors.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Haissaguerre et al (5,916,213), Whayne et al (6,402,746), and

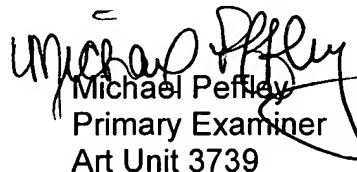
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Hall et al (6,290,699) all disclose devices that have electrodes deployed from an elongate member to a substantially flat, perpendicular orientation. Gough et al (5,672,173) disclose another device including a rigid cannula through which a plurality of electrodes are deployed for the treatment of tumors.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Michael Peffley  
Primary Examiner  
Art Unit 3739

mp  
September 27, 2005